DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

June 30, 2000

WARNING LETTER
CHI-25-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kin Wing Louie, President
Phoenix Bean Products
5438 N. Broadway
Chicago, IL 60640

Dear Mr. Louie:

An inspection of your tofu and bean sprout production facility by the U.S. Food and Drug Administration (FDA) May 22, 24-26, 2000, documented numerous insanitary conditions. These conditions cause your tofu and sprouts to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because they have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or, in the case of the spouts, whereby they may have been rendered injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your facility. Additional objectionable conditions observed include the following:

- Flies/insects observed in the tofu processing area and open unscreened doors to the exterior for extended periods of time.

- Open drains and standing water in the tofu and sprout processing areas.

- Bean sprouts stored for extended periods of time at room temperature in plastic bags on the floor in the sprout processing area.

- Use of unsuitable equipment, i.e. a cracked container with a plastic liner used for holding bean curd allowed the curd to protrude through the cracks onto the floor.

- Numerous improper employee practices, including employees performing multiple tasks handling unsanitary objects and then handling soybeans or raw bean sprouts without washing or sanitizing their hands.

At the close of the inspection you were issued a FDA-483, Inspectional Observations, listing deficiencies observed during the inspection. You reported and we observed corrections to some of the deficiencies. Further unspecified corrections were promised, however, as of this date we (FDA) have not been informed of improvements you have made.

The above listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence with each requirement of the Act and its regulations. We request that you take prompt action to correct all violations.

Please provide this office, within 15 days of receipt of this letter, a detailed response stating the actions you plan to take to correct and prevent the recurrence of these objectionable conditions. Provide the time within which the corrections will be completed, reasons why any corrective action can not be completed, and documentation to show that corrections have been made. Failure to take prompt action to correct all violations may result in regulatory action without further notice. Such action may include seizure and/or injunction.

Your reply should be directed to Paul A. Boehmer, Compliance Officer, at the Chicago District office.

Sincerely,

\s\
Raymond V. Mlecko
District Director